AMERICAN ASSOCIATION OF BLOOD BANKS

August 23, 2004

FDA Dockets Manager
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket 2004D-0193, May 25, 2004 Draft "Guidance for Industry: Eligibility Determination for Donor of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)"

Dear Dockets Manager:

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, developing and delivering programs and services to optimize patient and donor safety.

Thank you for the opportunity to comment on the May 25, 2004, Draft "Guidance for Industry: Eligibility Determination for Donor of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." The draft guidance is a comprehensive document that provides a great deal of useful information with regard to implementation of regulations promulgated by the final rule issued in the same day. We commend FDA for providing a well written document focused on the interests of cellular therapy programs.

We have the following comments:

HBsAg

The draft guidance document recommends permanent deferral of any cell and tissue donor who has a reactive screening test result for HBsAg. This creates a particular concern with respect to living stem cell and cord blood donors that test reactive to a screening test for HBsAg. FDA-licensed HBsAg confirmatory test kits are available to provide a definitive test result for HBsAg. However, according to the draft guidance document, a negative confirmatory test result for HBsAg cannot be used to overrule a reactive HbsAg screening result. AABB requests that FDA

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consider re-entry of stem cell and cord blood donors into the eligible donor pool if an FDA-licensed confirmatory test is performed, and the donor test sample is confirmed to be negative

CMV

The draft guidance document recommends that tissue establishments develop a procedure to govern the release of cells or tissue from donors whose specimens test reactive for CMV and to limit the use of such cells or tissue based on the CMV status of the recipient. With respect to the appropriateness of using cells or tissue from donors whose specimens test reactive for CMV, AABB recommends that the recipient's physician, rather than the tissue establishment, make this determination.

Physical Examination of a Living Donor

The draft guidance document recommends that a physical examination be performed on living donors to assess physical signs of relevant communicable diseases. AABB's concern relates to examination of living donors for physical signs suggestive of risk factors for sexually-transmitted diseases. AABB recognizes the importance of assessing donors for risk factors associated with relevant communicable diseases, but remains concerned that unnecessarily intrusive examinations could discourage donors. AABB requests that additional guidance be included to address the specific need for a physical examination in this regard.

Questions concerning these comments may be directed to M. Allene Carr-Greer, Deputy Director, Regulatory Affairs, AABB (**acarrgreer@aabb.org**)

Sincerely,

Karen Shoos Lipton, JD
Chief Executive Officer